

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 4

Complete if Known

Application Number	To be assigned
Filing Date	April 8, 2004
First Named Inventor	Khan et. al.
Group Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	3077-6420US

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
C/K		US- 4,977,244	12-11-1990	Muchmore et al.	
		US- 5,380,668	01-10-1995	Herron	
		US- 5,677,275	10-14-1997	Lunardi-Iskandar et al.	
		US- 5,851,997	12-22-1998	Harris	
		US- 5,877,148	03-02-1999	Lunardi-Iskandar et al.	
		US- 5,958,413	09-28-1999	Anagnostopoulos et al.	
		US- 5,968,513	10-19-1999	Gallo et al.	
		US- 5,997,871	12-07-1999	Gallo et al.	
		US- 6,319,504	11-20-2001	Gallo et al.	
		US- 6,319,504 B1	11-20-2001	Gallo et al.	
		US- 2002/0041871	04-11-2002	Brudnak	
		US- 2002/0064501	05-30-2002	Khan et al.	
		US- 6,489,296	12-03-2002	Grinnell et al.	
		US- 2003/0049273 A1	03-13-2003	Gallo et al.	
		US- 2003/0113733 A1	6-19-2003	Khan et al.	
		US- 6,583,109 B1	06-24-2003	Gallo et al.	
		US- 2003/0119720 A1	6-26-2003	Khan et al.	
		US- 6,596,688 B1	07-22-2003	Gallo et al.	
C/K		US- 6,620,416 B1	09-16-2003	Gallo et al.	
		US- 2003/186244 A1	10-02-2003	Margus et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
C/K		WO 99/59617	11-25-1999	Erasmus Universiteit		
		WO 97/49721	12-31-1997	University of Maryland		
		WO 01/10907 A2	02-15-2001	University of Maryland		
		WO 01/11048 A2	02-15-2001	University of Maryland		
		WO 01/72831	10-04-2001	Erasmus Universiteit		
C/K		2 706 772	12-30-1994	Vacsyn	no trans	
		EP 1 138 692 A1	10/04/2001	Erasmus Universiteit Rotterdam		

Examiner
SignatureDate
Considered

2/23/06

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	To be assigned
		Filing Date	April 8, 2004
		First Named Inventor	Khan et. al.
		Group Art Unit	To be assigned
		Examiner Name	To be assigned
(use as many sheets as necessary)		Attorney Docket Number	3077-6420US
Sheet	2	of	4

U.S. PATENT DOCUMENTS					
Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS						
Examiner Initials *	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
UK		EP 1 300 418	04-09-2003	Erasmus Universiteit Rotterdam		
UK		WO 98/35691	08-20-1998	Proscript, Inc.		
UK		WO 02/085117	10-31-2002	Eisai Co., Ltd.		
UK		DE 3715662	11-19-1987	The Wellcome Foundation Ltd.	no trans	
UK		DE 19953339	05-17-2001	Goldham Pharma GmbH	no trans	
UK		96/04008	02-15-1996	Government of the United States		
		97/49373	12-31-1997	University of Maryland Biotechnology Institute		
		97/49418	12-31-1997	University of Maryland Biotechnology Institute		
		97/49432	12-31-1997	University of Maryland Biotechnology Institute		
UK		WO 03/029292 A2	04-10-2003	Erasmus Universiteit Rotterdam		

Examiner Signature		Date Considered	2/23/06
-----------------------	--	--------------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	To be assigned
		Filing Date	April 8, 2004
		First Named Inventor	Khan et. al.
		Group Art Unit	To be assigned
		Examiner Name	To be assigned
Sheet 3 of 4	Attorney Docket Number	3077-6420US	

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
UK		CONNELLY et al., Biphasic Regulation of NF-kB Activity Underlies the Pro- and Anti-Inflammatory Actions of Nitric Oxide, The Journal of Immunology, 2001, pp. 3873-81, 166, The American Association of Immunologists, USA.	
		FRIEDLANDER, Tackling anthrax, Nature, November 8, 2001, pp. 160-61, Vol. 414.	
		MEDZHITOV, Toll-like Receptors and Innate Immunity, Nature Reviews/Immunology, November 2001, pp. 135-45, Vol. 1.	
		LANG et al., "Induction of apoptosis in Kaposi's sarcoma spindle cell cultures by the subunits of human chorionic gonadotropin", AIDS 1997, Vol. 11, No. 11, pp.1333-1340.	
		ISKANDAR et al., "Effects of a urinary factor from women in early pregnancy on HIV-1. SIV and associated disease", Nature Medicine, April 1998, Vol. 4, No. 4, pp. 428-434.	
		CHRISTMAN et al., Nuclear factor kappaB: a pivotal role in the systemic inflammatory response syndrome and new target for therapy, Intens Care Med, 1998, pp. 1131-38, Vol. 24.	
		JYONOUCHI et al., Proinflammatory and regulatory cytokine production associated with innate and adaptive immune responses in children with autism spectrum disorders and developmental regression, J Neuroim., 2001, pp. 170-79, Vol. 120.	
		KANUNGO et al., Advanced Maturation of Heteropneustes Fossilis (Bloch) by Oral Administration of Human Chorionic Gonadotropin, J. Adv. Zool., 1999, pp. 1-5, Vol. 20.	
		ROHRIG et al., Growth-stimulating Influence of Human Chorionic Gonadotropin (hCG) on Plasmodium falciparum in vitro, Zentralblatt Bakt, 1999, pp. 89-99, Vol. 289.	
		TAK et al., NF-kappaB: a key role in inflammatory diseases, J Clin Invest., 2001, pp. 7-11, Vol. 107.	
		TAN et al., The role of activation of nuclear factor-kappa B of rat brain in the pathogenesis of experimental allergic encephalomyelitis, Acta Physiol Sinica, 2003, pp. 58-64, Vol. 55.	
CPK		TOVEY et al., Mucosal Cytokine Therapy: Marked Antiviral and Antitumor Activity, J. Interferon Cytokine Res., 1999, pp. 911-21, Vol. 19.	

Examiner Signature		Date Considered	2/23/06
--------------------	--	-----------------	---------


* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	To be assigned
		Filing Date	April 8, 2004
		First Named Inventor	Khan et. al.
		Group Art Unit	To be assigned
		Examiner Name	To be assigned
Sheet 4 of 4	Attorney Docket Number	3077-6420US	

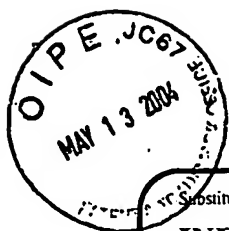
OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
UK		ALBINI, A., et al., "Old drugs as novel angiogenesis inhibitors: Preclinical studies with NAC, hCG, EGCG and somatostatin," 17 CLINICAL & EXPERIMENTAL METASTASIS 739 (1999).	
		BLACKWELL, Timothy S., et al., "The Role of Nuclear Factor-kB in Cytokine Gene Regulation," 17 AM. J. RESPIR. CELL MOL. BIOL. 3-9 (1997).	
		KELLER, S., et al., "Human Chorionic Gonadotropin (hCG) Is a Potent Angiogenic Factor for Uterine Endothelial Cells <i>in Vitro</i> ," 20(5-6) PLACENTA, page A37 (July 1999).	
		KHAN, Nisar A., et al., "Inhibition of Diabetes in NOD Mice by Human Pregnancy Factor," 62(12) HUMAN IMMUNOLOGY 1315-1323 (December 2001).	
		KHAN, Nisar A., et al., "Inhibition of Septic Shock in Mice by an Oligopeptide From the β -Chain of Human Chorionic Gonadotrophin Hormone," 63(1) HUMAN IMMUNOLOGY 1-7 (January 2002).	
		MUCHMORE et al., Immunoregulatory Properties of Fractions from Human Pregnancy Urine: Evidence that Human Chorionic Gonadotropin is not Responsible, The Journal of Immunology, March 1997, pp. 881-86, Vol. 118, No. 3.	
		MUCHMORE et al., Purification and Characterization of a Mannose-Containing Disaccharide Obtained from Human Pregnancy Urine, Journal of Experimental Medicine, December 1984, pp. 1672-85, Volume 160.	
		PATIL, A., et al., "The Study of the Effect of Human Chorionic Gonadotrophic (HCG) Hormone on the Survival of Adrenal Medulla Transplant in Brain. Preliminary Study," 87 ACTA NEUROCHIR (WIEN) 76-78 (1987).	
		SLATER, Lewis M., et al., "Decreased Mortality of Murine Graft-Versus-Host Disease by Human Chorionic gonadotropin," 23(1) TRANSPLANTATION 103-104 (January 1977).	
		WULCZYN, F. Gregory, et al., "The NF-kB/Rel and I κ B gene families: mediators of immune response and inflammation," 74(12) J. MOL. MED. 749-769 (1996).	
UK		YAMAMOTO, Y., et al., "Role of the NF-kB Pathway in the Pathogenesis of Human Disease States," 1(3) CURRENT MOLECULAR MEDICINE 287-296 (July 2001).	

Examiner Signature		Date Considered	2/23/06
-----------------------	---	--------------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 1

Complete if Known

Application Number	10/821,256
Filing Date	April 8, 2004
First Named Inventor	Khan et al.
Group Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	3077-6420US

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
Dupl		US-5,380,668	01-10-1995	Heron	
		US- 2003/0186244 A1	10-02-2003	Margus et al.	
		US- 2003/0113733 A1	06-19-2003	Khan et al.	
		US- 2003/0119720 A1	06-26-2003	Khan et al.	
		US- 2002/0064301 A1	03-30-2002	Khan et al.	
UK		US- 2003/0166556 A1	09-04-2003	Khan et al.	
		US- 2003/0215434 A1	11-20-2003	Khan et al.	
UK		US- 2003/0219425 A1	11-27-2003	Khan et al.	
		US- 2003/0220257 A1	11-27-2003	Benner et al.	
UK		US- 2003/0220258 A1	11-27-2003	Benner et al.	
		US- 2003/0220259 A1	11-27-2003	Benner et al.	
UK		US- 2003/0220260 A1	11-27-2003	Khan et al.	
		US- 2003/0220261 A1	11-27-2003	Khan et al.	
UK		US- 2003/0224995 A1	12-04-2003	Khan et al.	
		US- 2004/0013661 A1	01-22-2004	Wensvoort et al.	
		US-			
		US-			
		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		WO 03/029292 A2	04-10-2003	Erasmus Universiteit Rotterdam		

Examiner
SignatureDate
Considered

2/23/06

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08A (10-01)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

of

2

Complete if Known

Application Number	10/821.256
--------------------	------------

Filing Date	April 8, 2004
--------------------	----------------------

First Named Inventor	Benner et al.
----------------------	---------------

Group Art Unit	1644
----------------	------

Examiner Name	To be assigned
---------------	----------------

Attorney Docket Number	3077-6420US
------------------------	-------------

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

**Examiner
Signature**

Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated totake 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washngtn, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 223131450.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 2

Complete if Known

Application Number	10/821,256
Filing Date	April 8, 2004
First Named Inventor	Benner et al.
Group Art Unit	1644
Examiner Name	To be assigned
Attorney Docket Number	3077-6420UIS

NON PATENT LITERATURE DOCUMENTS

[illegible]

Examiner Signature		Date Considered	2/23/06
-----------------------	---	--------------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional).² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 223131450.